UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

VB

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/391,053	09/07/99	ROBL J	LA24A

023914 HM22/1114
MARLA J MATHIAS
BRISTOL-MYERS SQUIBB COMPANY
PATENT DEPARTMENT
P O BOX 4000
PRINCETON NJ 08543-4000

EXAMINER	
MOEZIE,F	
ART UNIT	**PAPER NUMBER**
1653	8

DATE MAILED: 11/14/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

	Application No.	Applicant(s)
Office Action Summary	09/391,053	Robl et al
	Examiner: F. T. Moezie	Group Art Unit: 1653

☒ Responsive to communication(s) filed on *9/7/99 and 9/22/00*.

☐ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *one* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) *1-20* is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☐ Claim(s) _____ is/are rejected.

☐ Claim(s) _____ is/are objected to.

☒ Claims *1-20* are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐approved ☐disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

DETAILED ACTION

STATUS OF CLAIMS

Claims 1-20 are pending in this Office action.

INCOMPLETE COMPLIANCE WITH THE AMINO ACID SEQUENCE LISTING

The sequence Listing submitted by applicant (9/22/00) has been entered, 10/2/00. However, the compliance is incomplete for the following reasons:

Not: Upon compliance with the requirements applicant must also amend the application to provide the SEQ ID NOS in THE SPECIFICATION (at least in the first occurance), in ALL EXAMPLES, TABLES and THE CLAIMS.

RESTRICTION REQUIREMENT

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-15, drawn to a method for treating diabetes in a mammal comprising administering to the mammal an aP2 inhibitor, classified in class 514, subclass depending on the structure elected for the aP2 inhibitor.

II. Claims 1-15, drawn to a method for treating insulin resistance in a mammal comprising administering to the mammal an aP2 inhibitor, classified in class 514, subclass depending on the structure elected for the aP2 inhibitor.

III. Claims 1-15, drawn to a method for treating obesity in a mammal comprising administering to the mammal an aP2 inhibitor, classified in class 514, subclass depending on the structure for the elected inhibitor.

IV. Claims 1-15, drawn to a method for treating hyperglycemia in a mammal comprising administering to the mammal an aP2 inhibitor, classified in class 514, subclass depending on the structure elected for the aP2 inhibitor.

V. Claims 1-15, drawn to a method for treating hyperinsulinemia in a mammal comprising administering to the mammal an aP2 inhibitor, classified in class 514, subclass depending on the structure elected for the aP2 inhibitor.

VI. Claims 1-15, drawn to a method for treating elevated fatty acids or glycerol or hypertriglyceridemia in a mammal comprising administering to the mammal an aP2 inhibitor, classified in class 514, subclass depending on the structure elected for the aP2 inhibitor.

VII. Claims 16-20, drawn to a composition and combination therapy in a method for treating diabetes in a mammal, comprising administering to the mammal a pharmaceutical composition comprising an aP2 inhibitor and an antidiabetic agent, classified in class 514, subclass depending on the structures elected for the aP2 ***and*** the antidiabetic agent.

VIII. Claims 16-20, drawn to a composition and combination therapy in a method for treating obesity in a mammal, comprising administering to the mammal a

pharmaceutical composition comprising an aP2 inhibitor ***and*** an antidiabetic agent, classified in class 514, subclass depending on the elected structures for the aP2 inhibitor and the antidiabetic agent.

IX. Claims 16-20, drawn to a composition and combination therapy in a method for treating hyperglycemia in a mammal comprising administering to the mammal a pharmaceutical composition comprising an aP2 inhibitor ***and*** an antidiabetic agent, classified in class 514, subclass depending on the elected structures for the aP2 and the antidiabetic agent.

X. Claims 16-20, drawn to a composition and combination therapy in a method for treating hyperinsulinemia in a mammal comprising administering to the mammal a pharmaceutical composition comprising an aP2 antagonist ***and*** an antidiabetic agent, classified in class 514, subclass depending on the structure elected for the aP2 inhibitor and the antidiabetic agent.

XI. Claims 16-20, drawn to a composition and combination therapy in a method for treating elevated blood levels of free fatty acids or glycerol in a mammal comprising administering to the mammal a pharmaceutical composition comprising an aP2 inhibitor ***and*** an antidiabetic agent, classified in class 514, subclass depending on the structure elected for the aP2 inhibitor and the antidiabetic agent.

XII. Claims 16-20, drawn to a composition and combination therapy in a method for treating hyper triglyceridemia in a mammal comprising administering to the

mammal a pharmaceutical composition comprising an aP2 antagonist ***and*** an antidiabetic agent, classified in class 514, subclass depending on the elected structure for the aP2 inhibitor and the antidiabetic agent.

Each one of the inventions above (I-XII) can be practiced using the following separate and distinct classes of aP2 inhibitor compounds:

A - an oxazole or an analogous ring,

B - a pyrimidine derivative, or

C - a pyridazinone derivative .

Therefore, each invention cited above (I-XII) is correctly divided into three (3) separate and distinct inventions depending on the compounds used (compounds having A structure, B structure or C structure). This results in three distinct invention for each one of the inventions cited above; namely inventions I-A, I-B and I-C for Invention I --- XII-A, XII-B, and XII-C for Invention XII. Consequently, the claims cited at pages 35-51 of the specification encompass 36 different and distinct inventions.

The inventions are distinct, each from the other because of the following reasons:

Any one of the Inventions I-A, I-B, I-C to VI-A, VI-B is distinct from the other. Inventions are distinct because the objectives are different in each method, the host being treated is different, the aP2 inhibitor compounds used as the pharmaceutical in different. Hence, the mode of operation, the protocol and the function of the pharmaceutical is different in each case. The consideration of patentability is different in each case. A reference which would obviate

under 35 USC 103 (a) claims drawn to a method of treating one of the conditions using a particular aP2 inhibitor compounds may not obviate claims drawn to other methods of treating - absent ancillary evidence. It would be an undue burden to examine all of the methods together in one application. .

Any one of the Inventions VII-A, VII-B, VII-C to XII-A, XII-B, XII-C, is distinct from the other. Inventions are distinct because the objectives are different in each case, the host being treated is different, the mode of operation is different, and the function of the pharmaceutical is different in each case. Moreover, the active pharmaceutical agents would have to be searched in the different class and subclasses and the computer and manual searches are not co-extensive. Further, a reference which would obviate claims drawn to one of the methods under 35 USC 103 (a) may not obviate any of the other method claims - absent ancillary evidence. It would be an undue burden to examine all of these methods in one application.

Any one of the inventions in Group I-A, I-B, I-C to -VI-A, VI-B, VI-C (using a different aP2 inhibitor in each invention) and each inventions in Group VII-A, VII-B, VII-C to XII-A, XII-B, XII-C (using a combination of an aP2 inhibitor and an antidiabetic agent) are distinct from the other. The inventions are distinct because the pharmaceuticals used are different, in addition to the various grounds of distinctness cited herein above. It would clearly be an undue burden on the examiner to examine all of the above inventions in one application. For the reasons cited above the restriction requirement as set forth herein above is proper.

Because these inventions are distinct for the reasons given above and the search required for any one invention (I-A --- XII-C) may not be required for other inventions, restriction for examination purposes as indicated is proper. Furthermore, it would be an undue burden to search for all of the inventions in one application.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

SPECIES ELECTION

Claims 1-20 are generic to a plurality of disclosed patentably distinct species of aP2 inhibitors comprising:

A) A myriad of species of an oxazole - cited in claims 11, 14 and 15,

B) Various species of a pyrimidine derivatives - cited in claims 12, 14 and 15, and

C) Species of a pyridazinone derivatives - cited in claims 13 and 15, for example.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species (A, B, or C) for the elected invention, together with the election of an ***ultimate specie*** of an aP2 inhibitor, even though this requirement is traversed. In the event applicant elects an invention drawn to a combination therapy (any one of Groups VII-A to XII-C) applicant is further required to ***additionally*** elect a species and an ***ultimate specie*** of the antidiabetic agent.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is advised that the reply to this requirement to be complete must include an ***election of the invention from one of Group I-A to XII-C*** along with the ***election of a second ultimate specie*** (for any of Group VII-A to XII-C) to be examined even though the requirement be traversed (37 CFR 1.143). Applicant is further required to ***indicate claims reading on the species in the elected invention*** and clearly show ***the complete structure for the ultimate specie(s).***

An ***ultimate specie*** of a compound is a compound wherein ***all*** of the variable parameters are accounted for.

Applicant is further advised to draw claim(s) to the elected invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any

amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to F.T. Moezie whose telephone number is (703) 305-4508.

F. T. MOEZIE, Ph.D.
PRIMARY EXAMINER
ART UNIT ~~166~~ 1653